Statements

Second Draft Statement on the potential health risks of Echinacea in the maternal diet

Introduction

1. As part of the Scientific Advisory Committee on Nutrition's (SACN) current programme of work on the potential risks from the maternal diet, the COT reviewed a scoping paper (TOX/2020/51) on commonly used herbal supplements during pregnancy. *Echinacea*, marketed for immune support and for the prevention or treatment of cold and flu-like symptoms, was among the supplements considered.

2. In December 2025, the Committee reviewed a first draft statement on the effects of *Echinacea* in the maternal diet (TOX/2025/45). Members were broadly satisfied with the risk characterisation and overall conclusions but recommended re-wording the final concluding sentence regarding the risk of *Echinacea* consumption during pregnancy. Members also requested that the risk characterisation section acknowledges that *Echinacea* preparations are complex mixtures, and that their risk assessment involves common challenges associated with mixture toxicity.

3. The Committee also commented on the organisation of the reproductive and developmental data, as well as the sequence in which the reproductive and developmental effects of *Echinacea* and the general adverse effects in humans were presented. It was suggested that the section on the reproductive and developmental effects of *Echinacea* should be discussed earlier in the statement after the toxicokinetics section in order to keep the maternal effects the focus of the statement. Members also advised that the colour-coding in Table 1 summarising the reproductive and developmental studies should be replaced with the terms insufficient, limited, and adequate more accurately reflect study quality and data sufficiency.

4. Further revisions were made to the statement to address Members' comments on the genotoxicity section, including clarification on the OECD compliance of the studies considered.

5. A second draft statement (Annex A) has been prepared, incorporating Members' comments and suggested revisions.

Questions for the Committee

The Committee are asked to consider the following questions:

a) Is the Committee satisfied with the layout and structure of the second

draft statement following the revisions made?

b) Does the Committee have any further comments on the second draft statement?

c) Given that herbal medicinal *Echinacea* products have defined compositions and regulatory oversight, while food supplements do not, and that regulatory authorities such as the EMA and MHRA do not recommend the use of medicinal *Echinacea* products during pregnancy or lactation due to insufficient safety data, does the Committee agree with the overall conclusion of the statement?

Secretariat

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